K063149

3. 510(K) SUMMARY

1. Applicant/Sponsor: T.O.A.D.S., LLC.
1226 Rowan St.
Louisville, KY 40203

MAR 0 8 2007

2. Contact Person: David Baughman
President
Email: David06@BaughmanGroup.com
Phone: (502) 581-8770

3. Proprietary Name: Orthodontic TAADS (Temporary Anatomical Anchor Device System)

4. Common Name: Screw type endosseous implants

5. Classification Name: Endosseous Implant
(21 CFR 872.3640)

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. AbsoAnchor (Orthodontic Microimplant) - Dentos Incorporated (K060126)
   b. Lin/Liou Orthodontic Mini Anchor System (LOMAS) (Sterile) – Mondeal Medical Systems GmbH (K050257)
   c. Temporary Orthodontic Anchor – Ortho Organizers, Inc. (K061266)
   d. tomas (Temporary Orthodontic Micro Anchorage System) pins – Dentaurum (K042965)

7. Device Description:
The Orthodontic TAADS Screws are single-use, screw-type, root-form endosseous dental implants designed for the anchoring of orthodontic appliances to the jaw. Each Orthodontic TAADS Screw model is designed for optimal holding power and function in a specific region of the mouth or jaw. Each model is also anodized for ease of identification through color. All of the TAADS devices are intended for immediate loading. All of the Orthodontic TAADS Screws are provided in sterile and non-sterile versions.

8. Intended Use:

   The Orthodontic TAADS Screws are intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. They are intended for temporary use and should be removed after orthodontic treatment has been completed. The screws are intended for single use only.

9. Summary of Technologies/Substantial Equivalence:

   The Orthodontic TAADS Screws have the same intended use and indications for use as, consist of the same materials as, and are similar in design to the following predicate devices: AbsoAnchor (Orthodontic Microimplant) - Dentos Incorporated; and Lin/Liou Orthodontic Mini Anchor System (LOMAS) (Sterile) – Mondeal. They are also similar in design and function to the Temporary Orthodontic Anchor – Ortho Organizers, Inc. and the tomas (Temporary Orthodontic Micro Anchorage System) pins – Dentaurum. Each of the Orthodontic TAADS Screw devices passes previously defined performance requirements and is thus considered to be as functionally safe and effective as the predicate devices.

10. Non-Clinical Testing:

    Dimensional comparison and engineering analysis were used to determine that the Orthodontic TAADS Screws are substantially equivalent to the predicate devices. Non-clinical (bench) testing was not performed.

11. Clinical Testing:

    Clinical testing was not necessary to determine substantial equivalence between the Orthodontic TAADS Screws and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Baughman
President
T.O.A.D.S., LLC
1226 Rowan Street
Louisville, Kentucky 40203

MAR 0 8 2007

Re: K063149
Trade/Device Name: Orthodontic TAADS (Temporary Anatomical Anchor Device System)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 16, 2007
Received: February 20, 2007

Dear Mr. Baughman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Orthodontic TAADS (Temporary Anatomical Anchor Device System)

Indications for Use:

The Orthodontic TAADS Screws are intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. They are intended for temporary use and should be removed after orthodontic treatment has been completed. The screws are intended for single use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) K063149